2. Responses and Recommendations to Questions Raised by the Agency in the Preamble of the Advance Notice of Proposed Rulemaking for Over-the-Counter Antigingivitis/Antiplaque Drug Products – Summary of Comments

- *It is P&G's position that any antigingivitis active ingredient that provides clinically meaningful antiplaque activity, whether a reduction in plaque mass, plaque metabolism or plaque virulence, should bear labeling and a statement of identity communicating an "antiplaque" benefit in addition to its "antigingivitis" statement of identity.*
  [Ref. Section 2.A. pp. 11-17]

- *Products that work by a mechanism other than a predominant plaque mass reduction to achieve their antigingivitis benefit should not be excluded from marketing under the OTC monograph and should be evaluated on a case-by-case basis. The benefit of having a safe and effective antigingivitis active ingredient in the marketplace that does not similarly reduce the accumulation of plaque mass in certain clinical settings does not carry any proven risk for the development of advancing gingival disease.* ***[Ref. Section 2.B. pp. 18-21]***

- *P&G's recommends, and regulations support, that combination products (anticaries fluoride ingredient and a Category I antigingivitis/antiplaque ingredient and/or a tooth desensitizer ingredient) should be permitted to be marketed during the rulemaking process as long as safety and effectiveness of each active ingredient can be assured. There are suitable performance tests in two of these monographs to assure the effectiveness of each active ingredient in the combination.*
  [Ref. Section 2.C. pp. 22-26]

- *The Subcommittee recognized the importance of establishing appropriate performance tests and reference standards for testing antigingivitis and antigingivitis/antiplaque actives under the monograph to ensure the effectiveness of products going into the marketplace. Based on the Subcommittee's recommendation, the Plaque Glycolysis and Regrowth Model (PGRM) for stannous fluoride and cetylpyridinium chloride and the Disk Retention Assay (DRA) for cetylpyridinium chloride are recommended performance tests under the monograph. Explicit information is included in this submission pertaining to testing protocols, effectiveness criteria, and statistical methods employed to conduct and analyze data from these tests.* ***[Ref. Section 2.D. pp. 27-41]***